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10/562,615

07/27/2006

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EXAMINER

SZNAIDMAN, MARCOS L

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

11/12/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

info@lmiplaw.com

| | | | |
|------------------------------|--------------------------------------|-----------------------------------|--|
| Office Action Summary | Application No. 10/562,615 | Applicant(s) KIM ET AL. | |
| | Examiner MARCOS SZNAIDMAN | Art Unit 1612 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17 and 20-21 (in part) is/are allowed.
- 6) ☒ Claim(s) 12-16, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is office action is in response to applicant's request for continued examination filed on August 31, 2009.

Continued Examination Under 37 CFR 1.114

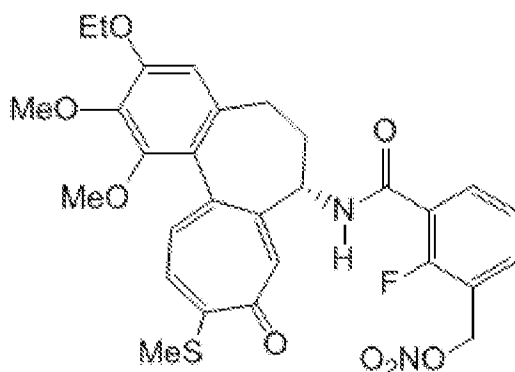
A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Status of Claims

Cancellation of claims 1, 3 and 5-11, and addition of claims 12-21 is acknowledged.

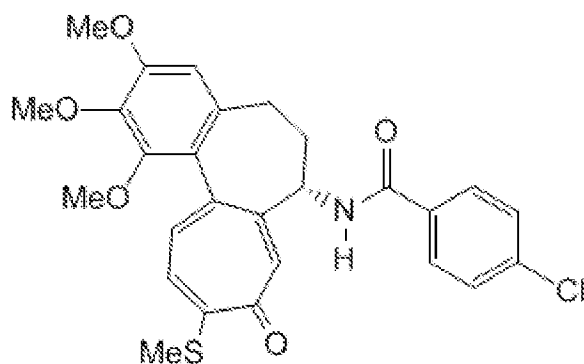
Claims 12-21 are currently pending and are the subject of this office action.

In the reply filed on June 3, 2008, Applicant elected the compound N-[7S-3-ethoxy-1,2-dimethoxy-10-methylsulfanyl-9-oxo-5,6,7,9-tetrahydro-benzo[a]heptalen-7-yl]-2-fluoro-3-nitoxymethyl-benzamide as the elected species, corresponding to the following structure:



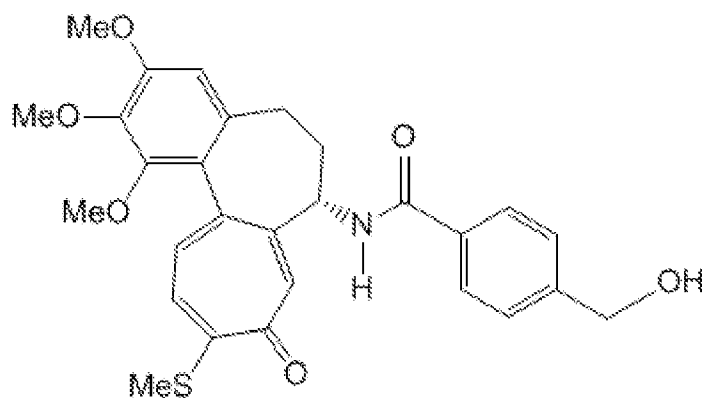
which is encompassed by the following claims: 12-21.

Since the above elected species was found free of prior art, in the Office Action mailed on August 27, 2008, the examination was expanded to the following species: 4-chloro-N-[5,6,7,9-tetrahydro-1,2,3-trimethoxy-10-(methylthio)-9-oxobenzo[a]heptalen-7-yl]-benzamide (CAS # 147950-73-0), which corresponds to the following structure:



However, due to Applicant's amendments the above species no longer is encompassed by the instant claims.

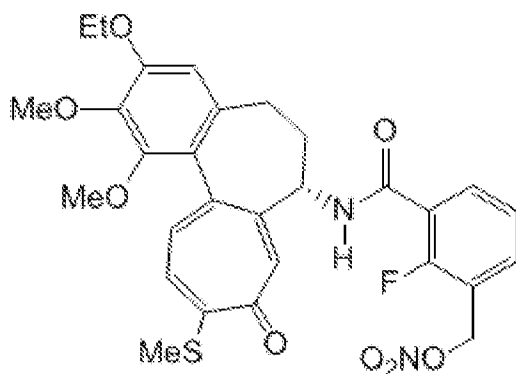
Since Applicant's elected species is free of prior art, and since the above expanded species is no longer encompassed by the instant claims, the search was expanded to the following species: 4-(hydroxymethyl(-N-[(7S)-5,6,7,9-tetrahydro-1,2,3-trimethoxy-10-(methylthio)-9-oxobenzo[a]heptalen-7-yl]-benzamide (CAS# 205805-07-8), which corresponds to the following structure:



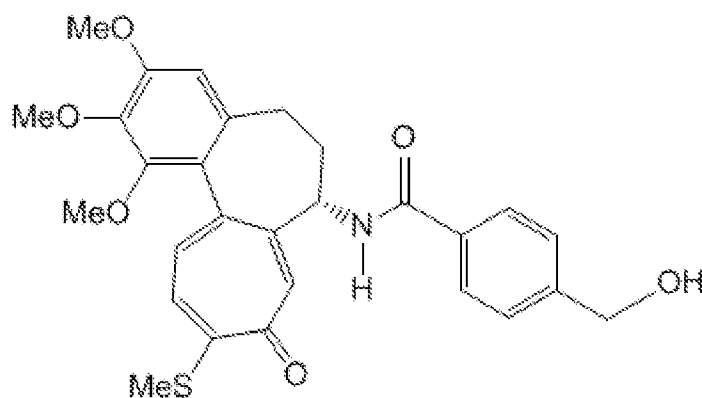
which is encompassed by claims 12-16, and 18-19.

In summary, the following species are under examination:

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elected by Applicant, and



expanded species.

Claims 12-21 read on one or both species and as a consequence are presently under examination.

Priority

The present application is a 371 of PCT/KR04/01518 filed on 06/23/2004, and claims priority to foreign Application: REPUBLIC OF KOREA 10-2003-00415467 filed on 06/25/2003.

Rejections and/or Objections and Response to Arguments

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102 (New Rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

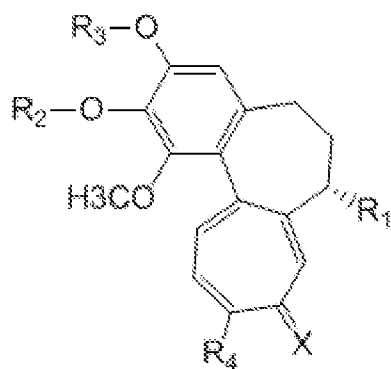
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-16, and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Guan et. al. (J. Med. Chem. (1988) 41:1956-1961).

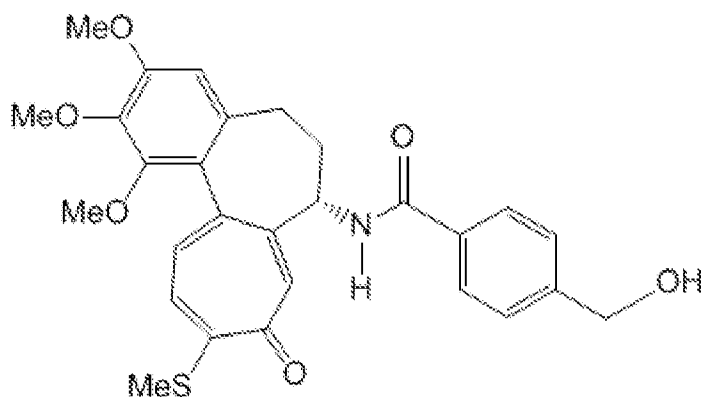
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Claims 12-16 recite a tricyclic derivative represented by the following Formula I or pharmaceutically acceptable salts thereof:



Formula I

For claims 12-16, Guan teaches the following compound: 4-(hydroxymethyl(-N-[(7S)-5,6,7,9-tetrahydro-1,2,3-trimethoxy-10-(methylthio)-9-oxobenzo[a]heptalen-7-yl]-benzamide (CAS# 205805-07-8, expanded species, see compound 25 on scheme 1 on page 1958), which corresponds to the following structure:



from now on compound B,
in which R₂ = R₃ = Methyl, R₄ = -SMe, X = O, R₁ is T1-B1, wherein T1 is -NHCO-, and
B1 is group (a) wherein R₆ = Hydrogen, R₇ = -OH, n₂ = 0 and n₃ = 1; which anticipates
claims 12-16.

Claims 18 and 19 further limit claim 12 wherein the compounds of claim 12 are
part of a composition further comprising a pharmaceutically acceptable excipient.

The statements: in claims 18 and 19: “an anticancer agent”, “anti-proliferation
agent” or “an angiogenesis inhibitor” are considered intended uses and do not add any
new limitation to the claim. *Catalina Mktg. Int’l, Inc. V. Coolsavings.com, Inc.*, 289 F.3d
801, 808, 62 USPQ2d 1781, 1785 (fed. Cir. 2002). “The recitation of a new intended
use for an old product does not make a claim to that old product patentable.” In re
Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

For claims 18 and 19, Guan further teaches that the compounds of the invention,
including compound B (expanded species), are pharmacologically active

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(Topoisomerase II inhibitors, see title for example) and were tested in an *in vitro* assay (see Table I on page 1957) in dilute water (a pharmaceutically acceptable excipient) solutions.

Withdrawn Rejections and/or Objections

Claims rejected under 35 USC 112, second paragraph.

Due to Applicant's cancellation of claims 5-6 and 8-11 the 112 2nd rejection is now moot.

Rejection under 35 USC 112, second paragraph is withdrawn.

Claims rejected under 35 USC 103 (a)

Due to Applicant's amendment and cancellation of claims, the 103 rejection is now moot.

Rejection under 35 USC 103 (a) is withdrawn.

Allowable Subject Matter

Claims 17 and 20-21 are allowable in part, but only insofar as it relates to the applicant elected species which has been found to be free of prior art.

Claims 17 and 20-21 are withdrawn in part, however, with regard to the non-elected subject matter contained therein.

Accordingly, claims 17 and 20-21 would be allowable at this time if amended to remove the non-elected subject matter.

Conclusion

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/
Examiner, Art Unit 1612
October 13, 2009.

/Frederick Krass/
Supervisory Patent Examiner, Art
Unit 1612